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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/517,210

03/09/2005

Evy Lundgren-Akerlund

10676.0010

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7590

08/10/2009

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EXAMINER

HADDAD, MAHER M

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

08/10/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,210	Applicant(s) LUNDGREN-AKERLUND, EVY	
	Examiner Maher M. Haddad	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 21 is/are pending in the application.
- 4a) Of the above claim(s) 5,7-14 and 16-18 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3,4,6 and 21 is/are allowed.
- 6) ☒ Claim(s) 1-2, 15 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/12/09 has been entered.
2. Claims 1-19 and 21 are pending.
3. Claims 5, 7-14 and 16-18 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.
4. Claims 1-4, 6, 15, 19 and 21 are under consideration in the instant application as they read on a method of identifying a mammalian mesenchymal stem cell using a marker comprising an integrin alpha 10 chain expressed on the cell surface of a mesenchymal stem cell or intracellular in mesenchymal stem cell as a marker for mammalian mesenchymal stem cells, wherein the expression is detected by an immunoassay.
5. Two telephonic attempts to reach Applicant's representative, dated 7/23/09 and 7/28/09, to allow the case did not result in returning the phone calls.
6. It is noted that claim 4 appears to be a repetitive claim because base claim 3 uses antibody to detect the integrin alpha 10 expression on the cell surface of cells of the sample or intracellularly in cells of the sample (i.e., protein). The recitation that "the expression in step c) is detected by detecting the integrin chain alpha 10 protein expression" in claim 4 appears to repeat what has been stated in base claim 3. Explanation is required.
7. The following is a quotation of the second paragraph of 35 U.S.C. 112.
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
8. Claims 1-2, 15 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
 - A. The recitation "a method using a marker comprising an integrin alpha 10 chain expressed on the cell surface of mesenchymal stem cells or intracellularly in mesenchymal stem cells as a marker for integrin alpha 10 chain expressing mammalian mesenchymal stem cells, wherein said method comprises the steps b) contacting the sample with an antibody which specifically binds integrin alpha 10 chain" in claim 1, is ambiguous and indefinite. The claim requires the use of an antibody which specifically binds integrin

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alpha 10 chain, not an integrin alpha 10 chain as a marker. The claim as written has circular logic; it simply repeats the claim that was already presented. Accordingly, the claim is indefinite.

- B. The recitation “A method for identification of integrin alpha 10 chain-expressing mammalian mesenchymal stem cells, comprising utilizing a marker comprising an integrin alpha 10 chain expressed on the cell surface of mesenchymal stem cells or intracellularly in mesenchymal stem cells, wherein said method comprises the steps of a) contacting a sample comprising mesenchymal stem cells with an antibody which specifically binds the marker, b) detecting the marker in cells of the sample, and c) identifying the cells in step b) as said integrin alpha 10 chain-expressing mammalian mesenchymal stem cells based on the presence of the marker” in claim 15, is ambiguous and indefinite. The claim utilizes an antibody which specifically binds alpha 10 chain to identify integrin alpha 10 chain-expressing mammalian mesenchymal stem cells. The claim as written has circular logic; it simply repeats the claim that was already presented. Accordingly, the claim is indefinite.

9. The declaration filed under 37 CFR 1.132 by Dr. Evy Lundgren-Akerlund on 6/12/09 is sufficient to overcome the prior rejection under 112(1) enablement. The declaration under ¶10 states that when I conducted the experiment disclosed in Example 3, I obtained the following results. FACS analysis of the bone marrow-derived cells after the first two weeks of culture without FGF-2 revealed that about 50% of cells expressed integrin alpha 10. After the additional two weeks in culture with or without FGF-2, FACS analysis of the FGF-2 treated cells revealed that 96% of the cells expressed integrin alpha 10 (see Example 3 and Figure 4). ¶12 of the declaration states that the results obtained for the non-treated cells have since been confirmed. The results are consistent with those described in Varas et al (Fig. 6) even though the overall percentage of integrin alpha 10 expressing cells may vary somewhat between experiments. Accordingly, FGF-2-untreated bone marrow-derived MSCs do express about 50% alpha 10 integrin chain.

It is noted that ¶2 of the declaration indicates that the *curriculum vitae* (CV) is provided as Appendix 1, however, there is no Appendix 1 attached to the declaration. The Examiner was not able to find Dr. Lundgren-Akerlund CV.

10. Claims 3-4, 6, and 21 are allowable.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 6, 2009

/Maher M. Haddad/
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Primary Examiner
Technology Center 1600